

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,	)	
	)	
Plaintiff,	)	C.A. No. 21-1015 (JLH)
	)	
v.	)	<b>DEMAND FOR JURY TRIAL</b>
	)	
SAREPTA THERAPEUTICS, INC.,	)	
	)	
Defendant.	)	
	)	
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA	)	[REDACTED]
,	)	
Defendant/Counter-	)	[REDACTED]
Plaintiffs,	)	
	)	
v.	)	REDACTED - PUBLIC VERSION
	)	
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.,	)	
	)	
Plaintiff/Counter	)	
Defendants.	)	

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.’S REPLY IN SUPPORT OF  
MOTION TO EXCLUDE OPINIONS OF DR. STEVEN DOWDY, PH. D.**

Dated: October 23, 2024

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Defendant NS Pharma, Inc.*

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NS's Daubert motion differs from its previous filings because the request is narrower: NS seeks to preclude Dr. Dowdy from testifying about post-priority date evidence only in support of his written description opinions. The law is clear that such testimony is not helpful and will only confuse the jury. And Dr. Dowdy himself agrees that "data that was not available [as of the priority date] would not reflect the understanding of a POSA at that time." D.I. 604-10 (Dowdy Suppl. Tr.). at 364:5-9.

Sarepta now tries to distance itself from Dr. Dowdy's admission, alleging he testified only that one particular post-priority reference Dr. Hastings reviewed was irrelevant to the exon 53 hotspot. D.I. 621 at 2. But Dr. Dowdy's testimony was not so limiting. *See* D.I. 621, Ex. 1 (Dowdy Suppl. Tr.) at 363:25-364:9. And, even it were, there is no principled basis to prohibit Dr. Hastings from relying on such evidence while allowing Dr. Dowdy.

Sarepta next claims that its "post-priority evidence show[s] that ASOs chosen from the 168-sequence genus dependably induce exon 53-skipping, consistent with the teaching of the patent" and "the post-priority evidence in this case merely confirms the structure-function correlation that was already set forth in the patent." D.I. 621 at 4-5. But the Federal Circuit has never identified such a "consistent with" or "confirmatory" exception to the "general rule [that] events subsequent to the priority date are irrelevant to [] the adequacy of the application's written description." *Ethanol Boosting Sys., LLC v. Ford Motor Co.*, 2019 WL 6307680, at \*2 (D. Del. Nov. 25, 2019). Indeed, the Federal Circuit held that a trier of fact "may not, however, use post-dated references as a source for later knowledge about later art-related facts . . . which did not exist on the filing date." *Bd. of Trustees of Leland Stanford Junior U. v. Chinese U. of Hong Kong*, 860 F.3d 1367, 1378 (Fed. Cir. 2017) (citing *In re Hogan*, 559 F.2d 595, 605 (Cust. & Pat. App. 1977)).

There can be no question that the later art-related facts on which Sarepta relies that purportedly are “consistent with” and “confirm” the disclosure in the specification did not exist on the filing date. Even under Sarepta’s view, the specification discloses “[o]nly one of the 168 antisense oligonucleotides defined by Claim 1.” D.I. 604-10 (Dowdy Suppl. Dep.) at 287:20-288:8. It defies logic for Sarepta to claim that Dr. Dowdy’s post-priority date evidence—which spans many other ASOs—does not “implicat[e] ‘later discovered species.’” See D.I. 621 at 4-5. Dr. Dowdy is improperly attempting to support the alleged existence of a structure-function correlation in 2005 by citing various ASOs that (undisputedly) no POSA had ever made or tested until years later.

Sarepta seeks to blur the important distinction between the confirmatory evidence that is irrelevant to written description and the evidence considered in *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017). But as this Court explained, “[i]n *Amgen*, the post-priority-date evidence – including the existence of the accused compound – was held admissible because it was relevant to the **number and nature** of species that actually exist within the claimed genus.” *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 367 (D. Del. 2019) (citing *Amgen*, 872 F.3d at 1373) (emphasis added). Here the confirmatory evidence Sarepta relies on is not relevant to the number nor the nature of the species. Sarepta cannot benefit from the *Amgen* exception.

Finally, this motion is not a rehash of NS’ prior motion *in limine* (D.I. 536-15). NS’s previous motion sought to more broadly exclude testimony from Dr. Dowdy about any post-priority date evidence, whereas here NS’s request is limited to written description. NS also relies heavily on a new and crucial admission from Dr. Dowdy’s supplemental deposition regarding the inapplicability of post-priority date evidence that was not available and could not have been cited

before. If the Court were to deny NS's motion because it is either duplicative of a previous request or not based on new evidence, then under the same logic the Court must deny Sarepta's co-pending *Daubert* motions as well.

October 23, 2024

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies that on October 23, 2024, a copy of the foregoing, NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE OPINIONS OF DR. STEVEN DOWDY, PH. D., which was filed under seal, was served via electronic mail on the following counsel of record:

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